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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,223	12/10/2001	Artur Mitterer	20695C-002100US	9005
7590 01/15/2004			EXAMINER	
KEVIN L. BASTIAN, ESQ. TOWNSEND AND TOWNSEND AND CREW 8TH FLOOR TWO EMBARCADERO CENTER SAN FRANCISCO, CA 94111-3834			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/006,223

Applicant(s)

MITTERER ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

1. Previously, claims 1-26 were pending in the application. In the prior action, mailed on June 17, 2003, claims 1-9 and 13-25 withdrawn, and claims 10-12, and 26 were under consideration and rejected. In the Response, filed on September 22, 2003, the Applicant cancelled claims 1-9, and 13-26, and amended claims 10-12. Amended claims 10-12 are the only claims currently pending in the application.
2. As this action raises new grounds of rejection not raised in the prior office action, this action is being made Non-Final.

### ***Requirement for Information***

3. Applicant's Response to the Requirement for Information, filed on October 31, 2003, is noted and has been considered by the Examiner.

### ***Specification***

4. **(Prior Objection- Withdrawn)** The specification was objected to in the prior action for the use of the trademark PRONASE without providing generic terminology for the product. In view of the amendments to the specification, the objection is withdrawn.

### ***Claim Objections***

5. **(Prior Objection- Withdrawn)** Claims 10 and 26 were objected to in the prior action because of the following informalities: the Applicant used the term SGT without first identifying

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what the acronym stands for. In view of the amendment to the claim providing the full name for SGT, the objection is withdrawn.

6. **(Prior Objection- Withdrawn)** Claim 12 was objected to in the prior action for reference to the composition with the tradename PRONASE without writing the word in uppercase letters and not providing a generic description of the product. The objection is withdrawn in view of the claim amendments correcting the deficiencies.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(New Rejection)** Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed composition obtained by contacting a PRONASE protease preparation with immobilized benzamidine and then eluted therefrom with arginine, does not reasonably provide enablement for such compositions wherein each of the immobilized affinity moiety and the eluting moiety is selected from any of an amidine, a guanidine, and an amine containing species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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The claims broadly cover SGT compositions having a specific activity of at least about  $25 \times 10^3$  U/mg and at least 95% purity. However, on pages 19-22 of the application, the specification indicates that whereas immobilization with benzamidine and elution with (at least) .6 M arginine results in a SGT composition with the claimed specific activity and purity. However, the same example demonstrates that immobilization and elution with benzamidine result in SGT compositions with a specific activity of only  $19 \times 10^3$  U/mg. Thus, the application indicates that only certain combinations of the indicated immobilization and elution moieties are capable of achieving the claimed compositions. The Applicant has not provided guidance to combinations, other than the benzamidine immobilization moiety and the at least .6M arginine elution moiety, that would be so capable. In view of the breadth of the claims, the limited teachings of the application, and the lack of predictability as to what combinations of the multiple available amidines, guanidines, and amine containing species would be capable of achieving SGT compositions with the claimed qualities, claim 12 is rejected as exceeding the scope of the specifications enabling disclosure.

***Claim Rejections - 35 USC § 102***

9. **(Prior Rejection- Withdrawn in part)** Claims 10 and 12 were rejected under 35 U.S.C. 102(b) as being anticipated by Koo et al., J Microbiol Biotech 8(4) :333-40. In view of the amendments to claim 10 requiring the presence of arginine in the solution, the rejection is withdrawn with reference to this claim.

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However, the rejection is maintained over claim 12. This is because, while the reference does not teach the actual purity level that was achieved, in view of the low yield of the SGT solution indicated (page 336, table 2) it is assumed that there was a high level of purity. Thus, because claim 12 does not require the presence of the arginine eluant, the rejection is maintained over this claim.

10. **(Prior Rejection- Withdrawn)** Claim 26 was rejected under 35 U.S.C. 102(b) as being anticipated by Kasai et al. J Chromatography 597: 3-18 (of record in the IDS). This claim reads on purified preparations of trypsin of at least 95% purity. This claim has been cancelled from the application. The rejection is therefore withdrawn.

#### ***Claim Rejections - 35 USC § 103***

11. **(Prior Rejection- Withdrawn)** Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Koo et al., in view of Kasai. Claim 11 describes a SGT preparation with a specific activity of at least about  $25 \times 10^3$  U/mg, and a purity of 95%. In view of the amendments to claim 10 the rejection is withdrawn.

#### ***Conclusion***

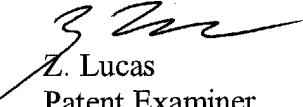
12. Claims 10 and 11 appear to be allowable over the prior art.


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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
January 2, 2004

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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1/12/04